

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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Echo Bay Pharmaceuticals, LLC,	:	
<i>Plaintiff,</i>	:	
	:	1:20-CV-06345-BCM
v.	:	
	:	<b>REPLY TO PLAINTIFF’S</b>
Torrent Pharma, Inc.,	:	<b>MEMORANDUM OF LAW IN</b>
<i>Defendant.</i>	:	<b>OPPOSITION TO DEFENDANT’S</b>
	:	<b>MOTION TO DISMISS SECOND</b>
	:	<b><u>AMENDED COMPLAINT</u></b>
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**INTRODUCTION**

Developing new generic pharmaceuticals is a difficult and uncertain process. A generic drug manufacturer must demonstrate bioequivalence to brand-name drugs—that is, that the proposed generic works in the human body in roughly the same way. It might appear easy to copy a brand-name drug, but the complex active molecules in modern drugs are often difficult to make and very slight variations can lead to huge differences in functionality. This is also just one component in the lengthy and complex process of obtaining FDA approval of an ANDA. In short, the path to a new generic drug is frequently a long and uncertain process.

The Co-Development Settlement Agreement (“CSA”) between Echo Bay Pharmaceuticals, LLC (“Echo Bay”) and Torrent Pharma, Inc. (“Torrent”) was drafted in recognition of this uncertainty. Deliberately, the CSA does not include any drug development timelines, milestones, or deadlines. The exclusive remedy provided in the CSA also recognizes the difficulty and uncertainty of generic drug development—a party that is unhappy with the pace of development may choose pursuant to Section 8.4 to take over development for itself. The parties deliberately structured these core provisions of the CSA this way in recognition of the reality of generic drug development.

In this lawsuit, Echo Bay is attempting to rewrite the CSA and add new remedies and obligations that the parties never contemplated. Echo Bay initially claimed that the CSA *implicitly* imposes *specific* communication and operational obligations to act “reasonably diligently and prudently” in developing certain Active Products. The CSA contains no such obligations, as addressed by Torrent’s prior motion to dismiss briefing.

Since Torrent’s initial motion to dismiss, Echo Bay has had more than a fair opportunity to scour the documentary record for breaches of the express terms of the contract -- Torrent has produced nearly 150,000 pages of documents in discovery in this case. But all Echo Bay has been able to muster are the handful of new allegations in the Second Amended Complaint that Torrent breached Section 8.4(a) of the CSA because it withdrew the ANDA for Fluocinonide, did not communicate the status of Fluocinonide to Echo Bay, and failed to subsequently assign development rights for Fluocinonide to Echo Bay.<sup>1</sup> Like its prior allegations, Echo Bay’s new allegations in the SAC do not state a claim for breach of contract. Assuming for purposes of this motion that Echo Bay’s allegations are true, Torrent could not have breached Section 8.4(a) even by withdrawing the ANDA for Fluocinonide because the CSA explicitly permits Torrent to cease development with or without communicating to Echo Bay.

But even if the alleged failure to communicate and withdrawal of the ANDA for Fluocinonide were breaches of the CSA, Echo Bay is once again asking the Court to rewrite the CSA by imposing a remedy -- money damages -- never contemplated by the parties. The CSA contains a single remedy for a party that is unhappy with development efforts -- Section 8.4(a). Section 8.4(a) provides that once either party (here, Torrent) has ceased development of any drug

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<sup>1</sup> As the Court might suspect, there is another side to this factual story—Torrent did not withdraw the ANDA for Fluocinonide and it has been attempting to communicate with Echo Bay about the status of this drug and others for years. Of course, Echo Bay’s allegations must be taken as true for purposes of this motion to dismiss pursuant to Rule 12(b)(6).

-- either by expressly notifying Echo Bay in writing, *or* impliedly by performing “no significant Development activities . . . over a given successive twelve (12) month period” -- then Echo Bay “may choose to continue to develop” the product. Echo Bay has not alleged that it ever chose to assume development of Fluocinonide, its sole remedy under the CSA. Echo Bay may now be dissatisfied with its bargain, but without electing to take over development of Fluocinonide for itself, it cannot state a claim for breach of Section 8.4(a).

Notwithstanding Echo Bay’s repeated attempts to sufficiently allege a breach of contract claim against Torrent, Echo Bay’s claims must be dismissed for failure to state a claim for damages. As discussed herein, Section 8.4 of the CSA is the exclusive remedy for any alleged breach of contract claim and Echo Bay is not entitled to monetary damages.<sup>2</sup>

### ARGUMENT

Echo Bay has not stated a claim for breach of Section 8.4(a) of the CSA. Assuming Echo Bay’s allegations are true (*i.e.* Torrent failed to develop Fluocinonide, terminated the corresponding ANDA<sup>3</sup>, and failed communicate as such to Echo Bay) Torrent is expressly permitted to cease development of an Active Drug without providing notice to Echo Bay. Section 8.4(a) carefully outlines the parties’ rights and obligations if one party ceases development. First, Torrent either provides written notification of its decision to cease development or it is deemed to have ceased development “if no significant Development activities with regard to a Product have occurred over a given successive twelve (12) month period.” ECF No. 91-1 at § 8.4(a). In such an event, Echo Bay “may choose to continue to develop [the product] and initially incur one hundred

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<sup>2</sup> Notably, Echo Bay spends more than one-third of its Opposition attempting to distinguish the cases cited by Torrent in its Memorandum of Law in Support of its Motion to Dismiss Second Amended Complaint. Torrent asserts that its case law is instructive and relevant, as the general contractual propositions asserted remain true regardless of the ultimate disposition of each given case.

<sup>3</sup> Torrent disputes that it terminated the ANDA for Fluocinonide. However, even assuming Echo Bay’s allegation is true, Echo Bay’s breach of contract claim fails because Section 8.4(a) grants either party the ability to cease development of an Active Product, which necessarily includes terminating the ANDA.

percent (100%) of the remaining Development Expenses for such Product.” *Id.* In other words, Torrent need not state expressly that it is ceasing development efforts. If no significant development activities occur in a twelve-month period, Echo Bay then must *choose* to pick up where Torrent left off and continue the development of Fluocinonide. Significantly, Echo Bay has not alleged in the SAC that it made this choice. This is fatal to its claim that Torrent breached Section 8.4(a).

In its Opposition, Echo Bay describes it as “laughable” and “non-sensical” that it should have to make an election in the face of an alleged lack of communication from Torrent. The Court should instead ask itself why the CSA has no communication requirement if communication is so central to the CSA’s exclusive remedy of Section 8.4. Section 3.1 of the CSA describes the process by which Torrent invoices Echo Bay for its share of Development Expenses “immediately on performance” of the relevant activity, which was consistently observed by Torrent. The CSA therefore provides a ready and regular window into the status of development efforts -- the regular cost-sharing invoices provided for in Section 3.1. Thus, even if Torrent refused to communicate with Echo Bay<sup>4</sup>, if Echo Bay did not receive development invoices for a twelve-month period, it would have had adequate notice to allow it to exercise its rights under Section 8.4. But in any event, the Court should not engage with Echo Bay’s request to rewrite the CSA. If regular communication was important to Echo Bay, it could have and should have negotiated communication requirements into the CSA. It did not do so. Its remorse at that decision does not give rise to a breach of contract claim.

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<sup>4</sup> This is false. Torrent has tried for years to communicate with Echo Bay without success.

In short, the SAC should be dismissed because all of Echo Bay's allegations -- its new allegations regarding Fluocinonide and its prior allegations -- represent an attempt to rewrite the carefully negotiated CSA:

- Echo Bay cannot rewrite the CSA to impose obligations upon Torrent to develop Active Products "reasonably and prudently." There is no such language in the CSA.
- Echo Bay cannot rewrite the CSA to impose communication requirements on Torrent that appear nowhere in the CSA. Similarly, the CSA expressly contemplates drug development ceasing without express notice to Echo Bay because Torrent is deemed to have ceased development if "no significant Development activities" occur within 12 months.
- Echo Bay cannot rewrite the CSA to avoid the exclusive remedy in Section 8.4(a). If Echo Bay is unhappy with how development has gone, it has the right to elect to take over development of Fluocinonide. Echo Bay has not done so, and instead wants this Court to give it money damages to which it is not entitled.

### **CONCLUSION**

In order to recover under the SAC, Echo Bay needs this Court to rewrite the agreement and impose obligations on Torrent that are not part of the CSA. The Court should reject Echo Bay's request to rewrite the CSA, and Torrent's Motion to Dismiss should be granted.

Dated: New York, New York  
September 21, 2021

By: /s/ Daniel M. Meier

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**CERTIFICATE OF SERVICE**

I, Daniel M. Meier, hereby certify that on the 21st day of September, 2021, I caused a true and correct copy of the foregoing Reply to Plaintiff's Memorandum of Law in Opposition to Defendant's Motion to Dismiss Second Amended Complaint to be served via the Court's CM/ECF system on those parties receiving Notice of Electronic Filing generated by the Court's CM/ECF system.

Dated: New York, New York  
September 21, 2021

By: /s/ Daniel M. Meier